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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,186	04/13/2000	Gilles Guichard	1487-25	7913

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	15

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/549,186	GUICHARD ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1,4,5,10-14,21,22,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6-9,15-20 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/716,249* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Office Action

Status of the Claims

1. Applicants' election with traverse of Group II (claims 2, 3, 6-9, 15-20, and 23), in Paper Nos. 9 and 14 is acknowledged. Upon further review of the previous restriction requirement, the Examiner would be willing to rejoin those inventions directed specifically toward the three variant FMDV serotype A12 immunodominant loop peptides corresponding to amino acids 141-159 as set forth on p. 76 of the disclosure. Thus, the claims should be amended to include the FP, FL, and SL peptides (SEQ ID NOS.: 7, 8, and 9, respectively). However, the remainder of the restriction requirement, as previously set forth in paper no. 8, is still proper and maintained. Applicants traverse and submit that it would not require an undue burden to examine the various peptides and other inventions simultaneously. This argument is not deemed to be persuasive for the reasons of record previously set forth in paper no. 8.

The regulations governing restriction requirements are set forth in 37 C.F.R. §§ 1.141 and 1.142. Two criteria currently exist for the determination of proper restriction requirements (see M.P.E.P. § 803): 1) The inventions must be independent (see M.P.E.P. §§ 802.01, 806.04, and 808.01) or distinct as claimed (see M.P.E.P. § 806.05); and 2) There must be a serious burden on the examiner if restriction is not required (see M.P.E.P. §§ 803.02, 806.04(a)-(j), 808.01(a), and 808.02). Establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. The following items adduce a *prima facie* showing of burden:

1) The inventions of Groups I-VIII display both separate

classifications and a separate status in the art as previously set forth in paper no. 8.

2) The inventions of Groups I-VIII are directed towards independent and distinct subject matter as clearly explained in paragraphs 2 through 9 of the restriction requirement. Accordingly, each invention will generate unique issues regarding novelty, patentability, and enablement.

3) Since the inventions disclosed *supra* are directed towards patentably distinct material, a search for one invention would not necessarily result in the identification of art that is concomitant with that required to address the issues generated by the other inventions.

Applicants arguments have been thoroughly considered but are not deemed persuasive for the reasons set forth *supra* and in the original restriction requirement (paper no. 8). **Accordingly, the requirement is still deemed to be proper and is therefore made FINAL.** Claims 1, 4, 5, 10-14, 21, 22, 24, and 25 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claim Objections

2. Claims 2, 3, 6-9, 15-20, and 23 are objected to because they fail to reflect the restriction requirement and election. Applicants are reminded of the restriction requirement as clearly set forth in paper no. 8 and further explained *supra*. Applicants are required to amend the claim language to reflect the restriction requirement (i.e., the claims should be directed toward the FP, FL, and SL peptides. Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 6-9, 15-20, and 23 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly directed toward vaccine compositions comprising immunoretroid peptides derived from three parent sequences (e.g., FMDV FP, FL, and SL peptides). However, the disclosure fails to provide adequate support for the instantly claimed invention.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide adequate guidance pertaining to the identification of suitable immunoretroid peptides that will retain the requisite immunogenicity and specificity of the parent

peptide. The claimed vaccine compositions comprise synthetic peptides that are derived from three parent FMDV serotype A12 parent peptides designated FP, FL, and SL. These peptides all correspond to amino acids 141-159 of the immunodominant loop. However, the claims may encompass chemical modifications at single or multiple amino acid locations throughout any given peptide. The skilled artisan cannot reasonably predict the effects of such changes on the immunological and biochemical properties of any given peptide (see item two below). Thus, the disclosure is silent pertaining to the identification of suitable modifications that will lead to a peptide that retains the native immunogenicity of the parent peptide.

2) The prior art teaches that the skilled artisan cannot reasonably predict how any given chemical modification will affect the immunological properties of any given peptide derivative (Benkirane *et al.*, 1993; Herve *et al.*, 1997). Many changes abrogate peptide activity. However, the disclosure fails to provide sufficient guidance pertaining to this major limitation.

3) The disclosure fails to provide any working embodiments. While generic formulas and methodologies are provided for the preparation of immunoretroid peptides, the disclosure fails to disclose the preparation of specific FMDV peptides. The disclosure fails to identify which portions of the immunodominant loop can be modified in such a manner that the original immunogenicity is maintained or improved.

Accordingly, when all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation to practice the claimed invention.

Correspondence

5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette,

1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

31 October, 2003